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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/788,787	02/27/2004	Jan Peter Sternby	GA-0267-US03	6157
24994	7590	11/28/2006	EXAMINER	
GAMBRO, INC PATENT DEPARTMENT 10810 W COLLINS AVE LAKEWOOD, CO 80215			DEAK, LESLIE R	
			ART UNIT	PAPER NUMBER
			3761	

DATE MAILED: 11/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/788,787	Applicant(s) STERNBY ET AL.	
	Examiner Leslie R. Deak	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 September 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 4,6-20,22,23,29 and 30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4,6-20,22,23,29 and 30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/27/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of the invention claimed in newly filed claim 29 in the reply filed on 12 September 2006 is acknowledged. Claims 4, 6-20, 22, 23, and 29-30 are currently pending.

### ***Double Patenting***

2. Applicant is advised that should claim 20 be found allowable, claim 23 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 4, 6-13, 22, 29, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,885,087 to Kopf.

In the specification and figures, Kopf discloses the device as claimed by applicant. With regard to claim 29, Kopf discloses a valve 16 illustrated as having a housing with an interior chamber (see FIGS 3, 4). The valve comprises 4 openings, A, B, C, D, that communicate with the chamber. The openings terminate in connectors that may be used as claimed by applicant. Applicant's recitation of a "blood" inlet and outlet and "circuit" inlet and outlet are considered by the examiner to be a recitation of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed fails to differentiate from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, the inlet and outlet projections illustrated by Kopf are capable of being connected to a blood system and a circuit system, wherein the circuit is illustrated as being connected to a hollow fiber mass transfer device that may be used as a dialyzer, thereby meeting the limitations of the claims. (See column 8, lines 58-58, column 5, lines 33-36, FIG 5.) Kopf further discloses that the valve 16 comprises a member or vane 17 that is capable of movement to change the direction of flow through the valve. Applicant's recitation that the valve "does not ever" fully block the valve openings is considered by the examiner to be a statement of the intended use of the device. See explanation above. It is the position of the examiner that the valve member 17 disclosed by Kopf is capable of being rotated such that it does not fully block any one of the openings (such as in a partial rotation), thereby meeting the limitations of the claims.

With regard to claim 30, Kopf discloses that the valve 16 may be connected to a hollow fiber mass transfer device 12 that is capable of being used as a dialyzer (see

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column 5, lines 33-36). The mass transfer device has two compartments, separated by semipermeable hollow fiber membranes, which corresponds to applicant's blood compartment and dialyzer fluid compartment (see column 6, lines 55-68). Valve connectors B and D are illustrated as connecting, via lines 14, 18 to the mass transfer device 12, meeting the limitations of the claims.

With regard to claim 4, examiner considers applicant's recitation that the valve is "arranged to" perform specific flow control function to be a recitation of the intended use of the valve. . It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed fails to differentiate from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, applicant fails to recite any structural features that allow for such an "arrangement," and the examiner considers the valve disclosed by Kopf to be capable of such an arrangement, meeting the limitations of the claim.

With regard to claim 6-8, Kopf specifically discloses that valve member 17 is pivotable or rotatable within housing 16 (see column 8, lines 28-48). With regard to claims 7 and 8, examiner considers applicant's recitation with regard to the positioning of the valve to be a recitation of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed fails to differentiate from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, the valve disclosed by Kopf is capable of rotating and opening and closing passages as claimed by applicant, thereby meeting the limitations of the claims.

With regard to claims 9-10 and 12-13, Kopf illustrates a cylindrical valve housing 16 with openings A, B, C, D, disposed at 90 degree angles from one another, making them diametrically opposite (see FIGS 3-4). The valve member 17 divides the chamber into two semi-circular-shaped portions, meeting the limitations of the claims.

With regard to claims 11 and 22, Kopf illustrates that the valve has connectors (unlabeled extensions from valve 16 in FIG 2) that connect to lines 16, 18, 22, and 32 for connection to the dialyzer (see FIG 2).

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,885,087 to Kopf in view of US 5,443,453 to Walker et al.

With regard to claim 14, Kopf discloses the device substantially as claimed by applicant (see rejection above) with the exception of a wing projection from the valve. Walker discloses a multi-way valve that has a rotatable valve member 13 within body 11, the rotation of which opens and closes various fluid paths (see column 3, lines 39-62). The valve member comprises handle 12 that extends outside the valve chamber for visual identification of valve position (see column 1, lines 50-60). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was

made to add a handle or wing 12 as disclosed by Walker to the valve as disclosed by Kopf, in order to provide a visual and tactile indication of the valve position, as taught by Walker (see column 1, lines 50-60).

With regard to claims 15 and 16, Kopf discloses the device substantially as claimed by applicant with the exception of a shoulder and a groove to control movement of the valve. Walker specifically discloses that the valve comprises a shoulder 28 the body that interacts with shoulder 27 on the stem to control movement of the valve (see FIG 3, column 4, lines 36-39). Though Walker does not specifically disclose a groove, the absence of material that allows the rotation of the valve to the point of shoulder 27 is considered by the examiner to correspond to applicant's claimed groove, meeting the limitations of the claims. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add a shoulder and a groove as disclosed by Walker to the valve disclosed by Kopf in order to prevent movement of the valve beyond a certain prescribed position, as taught by Walker (see column 4, lines 36-39).

7. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,885,087 to Kopf in view of US 5,443,453 to Walker et al, further in view of US 4,593,717 to Levasseur.

In the specification and the figures, Kopf and Walker disclose the device substantially as claimed by applicant (see rejection above) with the exception of recesses that define valve positions. Levasseur discloses a multi-way valve with a rotating valve stem 40 that puts various passages in fluid communication with one

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another (see column 2, lines 57-67). Levasseur further discloses that the valve system comprises a detent mechanism to locate the valve stem in the proper position once a particular flow mode is selected (see column 3, lines 42-64). The detent mechanism comprises a number of recesses 70 that cooperate with slot or groove 76. When the valve stem is in the proper position, rod or shoulder 72 drops into the corresponding recess 70 to maintain the valve in the proper position until the operator selects another flow mode. Therefore, it would have been obvious to add the detent mechanism with recesses as disclosed by Levasseur to the valve with groove and shoulder as disclosed by Kopf and Walker in order to maintain the valve in the proper position according to the selected flow mode, as taught by Levasseur (see column 3, lines 42-64).

8. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,885,087 to Kopf in view of US 4,593,717 to Levasseur.

In the specification and figures, Kopf discloses the device substantially as claimed by applicant (see rejection above) with the exception of the non-symmetrical position of the valve openings and connectors. Levasseur discloses a multi-way valve with a rotating valve stem 40 that puts various passages in fluid communication with one another in a non-90-degree configuration (see column 2, lines 57-67). Levasseur specifically discloses that entrapment of bubbles in a 90-degree flow conduit is more likely than that in an angled conduit (see column 1, lines 20-25). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide flow passages at a less than 90-degree angle as disclosed by



Levasseur in the valve assembly disclosed by Kopf, in order to prevent bubble entrapment, as taught by Levasseur (see column 1, lines 20-25).

9. Claims 20 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,885,087 to Kopf in view of US 2,703,586 to Asker.

In the specification and figures, Kopf discloses the device substantially as claimed by applicant (see rejection above) with the exception of the size of the valve member being smaller than the size of the openings. Asker discloses a multi-port valve 10 with rotating valve vane 37 that rotates about a central axis to place various ports in fluid communication with one another (see column 1, lines 15-40, column 2, lines 18-57). Asker specifically discloses that the rotor is most desirably a relatively thin vane, which Asker illustrates as smaller than the width of the openings (see FIG 2). Therefore, it would have been an obvious matter of design choice to construct the valve member disclosed by Kopf smaller than the size of the valve openings as disclosed by Asker, since such a modification would have involved a mere change in the size of a component, and is noted by Asker to be a desirable design for such a valve. A change in size is generally recognized as being within the level of ordinary skill in the art. See MPEP 2144.04.

### ***Conclusion***

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

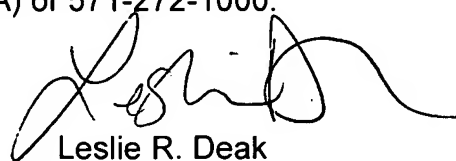
- a. US 6,308,737                      Kritiviski

- i. Dialysis reversing valve
- b. US 6,743,193 Brugger et al
- ii. Hermetic flow selector valve

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leslie R. Deak  
Patent Examiner  
Art Unit 3761  
20 November 2006